PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Herceptin® 21 mg/mL IV Infusion

Bacteriostatic Water for Injection for Herceptin® Diluent for injection

The active substance is Trastuzumab

Sugar free

Read all of this leaflet carefully before you start receiving Herceptin

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

1. What Herceptin is and what it is used for
2. What you need to know before you are given Herceptin
3. How Herceptin will be given to you
4. Possible side effects
5. How to store Herceptin
6. Contents of the pack and other information

1. What Herceptin is and what it is used for

Herceptin contains the active substance trastuzumab, which is a humanized monoclonal antibody.

Herceptin is used for the treatment of breast and gastric cancer if you have high levels of a protein called HER2 and your chemotherapy is finished.

If you have metastatic breast cancer (MBC), Herceptin is indicated:

- As monotherapy if you have received at least two chemotherapy regimens for your metastatic disease.
- In combination with paclitaxel or docetaxel if you have not received chemotherapy for your metastatic disease.
- In combination with an aromatase inhibitor if you have hormone-receptor positive metastatic breast cancer.

If you have early breast cancer (EBC), Herceptin is indicated:

- Following surgery, chemotherapy (neoadjuvant or adjuvant)and radiotherapy (if applicable); and
- In combination with adjuvant chemotherapy consisting of docetaxel and carboplatin.
- In combination with adjuvant chemotherapy followed by adjuvant Herceptin 21 mg/ml IV, for locally advanced breast cancer.

If you have metastatic gastric cancer (MGC), Herceptin is indicated:

- In combination with capecitabine or 5-fluorouracil and cisplatin for metastatic cancer of the stomach or gastro-oesophageal junction if you have not received prior anti-cancer treatment for your metastatic disease.

2. What you need to know before you are given Herceptin

You should not be given Herceptin:

- If you are allergic to trastuzumab, to murine (mouse) proteins, or to any of the other ingredients of Herceptin.
- If you have breathing problems at rest or if you need oxygen treatment.
- If you are pregnant or breastfeeding your baby.

Talk to your doctor, pharmacist or nurse before you are given Herceptin:

- If you have or have had heart failure, coronary artery disease, heart valve disease (heart murmurs) or high blood pressure. This is because Herceptin can cause heart failure.
- If you have ever had chemotherapy with a medicine called doxorubicin or a medicine related to doxorubicin (your doctor can advise you on this). Herceptin and doxorubicin-like medicines can damage heart muscle and increase the risk of heart problems when receiving Herceptin.
- If you are breathless. Herceptin can cause breathing difficulties. This could be more serious if you are already breathless.
- If you have ever had any other treatment for cancer.

Your doctor will closely supervise your therapy with Herceptin. Treatment with Herceptin may affect the heart. Therefore, your heart function will be checked before and during the treatment with Herceptin. If you develop any signs of heart failure (that is, inadequate pumping of blood by the heart), you may have to stop Herceptin.

It may take up to 7 months for Herceptin to be removed from the body. Therefore, you should tell your doctor or pharmacist that you have had Herceptin if you start any new medicine in the 7 months after stopping treatment.

Use in children and adolescents

Herceptin is not recommended for anyone under the age of 18 years.

Other medicines and Herceptin

Please tell your doctor or pharmacist that you have had Herceptin if you start any medicine in the 7 months after stopping treatment with Herceptin. Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Pregnancy and Breastfeeding

You must not use Herceptin if you are pregnant. Herceptin can cause harm to the foetus (unborn baby), in some cases death to the foetus, when taken by a pregnant woman.

Before starting treatment, you must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant.

If you are a woman or a man receiving Herceptin, you are advised to use a highly effective form of contraception, including a barrier method, while receiving Herceptin and for at least 7 months after your last Herceptin dose.

Do not breastfeed your baby during Herceptin therapy and for 7 months after the last dose of Herceptin.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before being given Herceptin.

Driving and using machines

It is not known whether Herceptin could affect your ability to drive a car or operate machinery. However, if you experience symptoms, such as chills or fever, during an infusion of Herceptin, you should not drive or use machines until these symptoms disappear.

3. How Herceptin will be given to you

Dosage and frequency of administration

Herceptin is given as an intravenous infusion (“drip”) directly into your veins. Your doctor will prescribe a dose and treatment regimen that is right for you. The number of infusions you receive will depend on how you respond to the treatment. Your doctor will discuss this with you.

If you stop using Herceptin

Do not stop using this medicine without talking to your doctor first. All doses should be taken at the right time every week or every three weeks (depending on your dosing schedule). This helps your medicine work as well as it can.

It may take up to 7 months for Herceptin to be removed from your body. Therefore your doctor may decide to continue to check your heart functions, even after you finish treatment.

4. Possible side effects

Herceptin can cause side effects. Some of these side effects may be serious and may lead to hospitalisation or death. Not all side effects reported for Herceptin are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Herceptin, please consult your doctor, pharmacist or healthcare professional for advice.

Herceptin administration can result in severe hypersensitivity reactions (including anaphylaxis), infusion reactions and pulmonary (lung/respiratory) events. These may cause death. In most cases, these symptoms occurred during or within 24 hours of administration of Herceptin. During a Herceptin infusion, chills, fever and other flu-like symptoms may occur. These are very common. They mainly occur with the first infusion and are temporary. Other infusion-related symptoms are: feeling sick (nausea), vomiting, pain, increased muscle tension and shaking, headache, dizziness, breathing difficulties, wheezing, high or low blood pressure, heart rhythm disturbances (palpitations, heart fluttering or irregular heart beat), swelling of the face and lips, rash and feeling tired. These symptoms can be serious and some patients have died (see “Warnings and precautions”).

- You should tell your doctor immediately if you notice:
- breathlessness (including breathlessness at night)
- cough
- swelling of the lips, face or throat

- palpitations (hear fluttering or irregular heart beat)
- fluid retention (swelling) in the legs or arms or

Heart problems can occur and are serious. They include weakening of the heart muscle possibly leading to heart problems, and heart rhythm disturbances. Your doctor will monitor your heart regularly during treatment. Taking Herceptin can result in serious and potentially deadly lung problems, including:

- A severe shortness of breath
- Too little oxygen in the body
- Weakening of the heart valve between the heart and the lungs
- Swelling of the lungs
- Fluid in or around the lungs
- Scarring of the lungs

Problems like these may occur after an infusion of Herceptin.

Some effects mainly occur with the first infusion and during the first few hours after the start of the infusion. Occasionally, symptoms start later than six hours after the infusion begins. Sometimes, symptoms may improve and then get worse later. If either of these happens to you, contact your doctor immediatel

Frequent side effects of Herceptin are:

swelling of the face and lips	Wheezing
heart rhythm disturbances	Diarrhea
Weakness	Skin rashes
Chest pain	Abdominal pain
Joint pain	Muscle pain
Allergic reactions	itchiness
Anormal blood counts (anaemia low platelet count and low white blood count)	Dry mouth and skin
Constipation	dry watery eyes
Heart burn (dyspepsia)	sweating
infections including bladder and skin infections	Feeling weak and unwell
shingles	anxiety
Inflammation of the breast	depression
inflammation of the pancreas or liver	Abnormal thinking
kidney disorder	dizziness
increased muscle tone /tension (hypertonia)	Loss of appetite
tremor	Weight loss
numbness or tingling of the fingers and toes.	Altered taste
Nail disorders	asthma

Hair loss	lung disorders
inability to sleep (insomnia)	back pain
sleepiness (somnolence)	neck pain
Nose bleed	bone pain
bruising	acne
haemorrhoids	Leg cramps
hand-foot syndrome (palms of hands or soles of feet tingle, become numb, painful, swollen or red	
arthritis	Blood pressure changes
Anaphylactic reactions	Loss of eyelashes
Failure of lungs to develop the womb	Abnormal kidney

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 : By reporting side effects, you can help provide more information on the safety of Herceptin.

5. How to store Herceptin

Store out of reach of children.

Vials must be stored in a refrigerator (2 □C - 8 □C).

Do not use this medicine after the expiry date (EXP) stated on the outer carton and on the vial label.

Disposal of unused/expired medicine:

The release of pharmaceuticals in the environment should be minimised. Medicines should not be disposed of via wastewater and disposal through household waste should be avoided. Use established collection systems, if available in your location.

6. Contents of the pack and other information

What Herceptin contains

The active substance is trastuzumab, which is supplied in single or multidose use vials. When reconstituted Herceptin contains 21 mg trastuzumab per mL. The other ingredients are αα-trehalose, l-histadine, polysorbate 20 and water for injection.

Bacteriostatic Water for Injection for Herceptin: The solvent for reconstitution of Herceptin for use with the multidose vial, contains bacteriostatic water with 1,1 % m/v benzyl alcohol, as preservative. The lyophilised powder for the 440 mg multi-dose vial must be reconstituted and diluted before use, using the Bacteriostatic water for injection for Herceptin. The 150 mg single-dose vial lyophillised powder must be reconstituted and diluted before use, using sterile water for injection.

What Herceptin looks like and contents of the pack

Multidose vial: Each pack of Herceptin 440 mg multidose vials contains a white to pale yellow lyophilised ("freeze-dried") powder. Each pack contains one vial of Herceptin in a 50 mL clear, colourless glass type 1 vial with a grey siliconised butyl rubber stopper, sealed with a silver aluminium cap and a green flip-off disk **and**

One vial of Bacteriostatic water for injection for Herceptin in a 20 mL clear, colourless glass type 1 vial with a grey butyl rubber stopper, sealed with a silver aluminium cap and white flip-off disk.

The Bacteriostatic water for injection for Herceptin is a clear, colourless liquid.

Single-dose vial: Each pack of Herceptin 150 mg single-dose vials contains a white to pale yellow lyophillised ("freeze dried") powder. Each pack contains one vial of Herceptin powder in a 15 mL clear, colourless glass type 1 vial with a grey siliconized butyl rubber stopper, sealed with a silver aluminium cap and red flip-off disk.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Registration numbers

Herceptin 21 mg/ml IV: 34/26/0419

Bacteriostatic Water for Injection for Herceptin: 34/32.4/0420

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Botswana	S2 BOT0901519
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Zimbabwe	PP 2014/9.7/4830